

Purpose of Meeting:

Review Section 3 Deficiencies and Discuss Resubmission of Chlormequat Chloride petition by Eastman/Taminco

Meeting Date:

June 4, 2019 from 2:30 – 3:00 pm

Attendees:

Heather Garvie – EPA – garvie.heather@epa.gov

Lindsay Roe – EPA – [[HYPERLINK "mailto:roe.lindsay@epa.gov"](mailto:roe.lindsay@epa.gov)]

Cynthia Giles-Parker – EPA – [[HYPERLINK "mailto:giles-parker.cynthia@epa.gov"](mailto:giles-parker.cynthia@epa.gov)]

Jean Holmes – EPA – holmes.jean@epa.gov

Katrina White – EPA – [[HYPERLINK "mailto:white.katrina@epa.gov"](mailto:white.katrina@epa.gov)]

Karen Milians – EPA – [[HYPERLINK "mailto:milians.karen@epa.gov"](mailto:milians.karen@epa.gov)]

Cameron Douglass – EPA – [[HYPERLINK "mailto:douglass.cameron@epa.gov"](mailto:douglass.cameron@epa.gov)]

Jessica McLaughlin – Eastman/Taminco – [[HYPERLINK "mailto:jessicamclaughlin@eastman.com"](mailto:jessicamclaughlin@eastman.com)]

John Hott – Eastman/Taminco – [[HYPERLINK "mailto:johnhott@eastman.com"](mailto:johnhott@eastman.com)]

Rebecca Currie – Eastman/Taminco – [[HYPERLINK "mailto:rebeccacurrie@eastman.com"](mailto:rebeccacurrie@eastman.com)]

Juli Mann – Steptoe & Johnson (Consultant to Eastman/Taminco) - [[HYPERLINK "mailto:JMann@steptoe.com"](mailto:JMann@steptoe.com)]

Notes:

Text in Black is information that was discussed during the meeting

Text in Red is information that was sent by Heather Garvie as a post-meeting follow up

Meeting notes:

- Taminco outlined the history of chlormequat chloride, regarding their interest in the chemical.
 - December 7, 2018 – Submission of Section 3 Registration to EPA
 - March 26, 2019 – Received 10 Day Deficiency Letter from EPA
 - March 27, 2019 – Eastman submitted response to 10 Day Deficiency Letter
 - May 8, 2019 – Received rejection letter from EPA
- Taminco outlined the deficiencies that need to be fulfilled to successfully pass a future technical screen for their Section 3 registration of chlormequat chloride for first food use.
 - 835.2410 – Soil Photolysis
 - 835.4200 – The company does not plan to conduct a study. A waiver will be requested to address this guideline requirement. The agency will not evaluate the waiver request without a complete application in-house for review.
 - 850.4500 – Non-Vascular Aquatic Plant Toxicity - marine diatom (*Skeletonema costatum*)
 - 850.4500 – Non-Vascular Aquatic Plant Toxicity - freshwater diatom (*Skeletonema costatum*~~*Navicula pelliculosa*~~)
 - 850.1350 – Chronic Saltwater Vertebrate
 - 850.1400 – Chronic Saltwater Invertebrate

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Commented [GC1]: Anaerobic soil and aquatic metabolism studies need to be evaluated before a decision can be made on the waiver.

Commented [JBA2R1]: Clarification- On behalf of Jean Holmes: The data waiver is for the anaerobic soil metabolism study. We would need to evaluate the anaerobic aquatic metabolism study to see if the anaerobic soil metabolism study can be waived.

Commented [GC3]: There are 2 species required?

Commented [DC4R3]: Corrected to show that testing with separate marine and freshwater species is required

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- 850.6100 – The associated Independent Laboratory Validation for the Environmental Chemistry Method in water. The agency acknowledges this study, but it will not be reviewed until the agency has a complete application.
- Taminco will conduct all the noted deficiencies listed above in addition to:
 - 850.4500 – Non-Vascular Aquatic Plant Toxicity - freshwater green alga (*Raphidocelis subcapitata*)
- Taminco expects to resubmit a Section 3 registration petition for a TGA of chlormequat chloride and an end-use product containing 54.78% chlormequat chloride in early 2020.
- Taminco confirmed they will submit a waiver request for the Anaerobic Soil Metabolism to support their Section 3 submission.
 - EPA agreed the submission of an Aerobic Soil Metabolism study, an Anaerobic Aquatic Metabolism study, and a scientific Anaerobic Soil Metabolism study waiver would be a strong package to support their product registration.
- EPA suggested submitting the scientific Anaerobic Soil Metabolism study waiver as a PRIA R124 action for absolute confirmation of the waiver's acceptability.
 - This has a 6-month timing and \$2,530 fee.
- EPA confirmed, if Taminco's label uses and data packet remain the same for their future Section 3 petition and Taminco addresses all the deficiencies outlined in the May 8, 2019 rejection letter, no additional data will be required to pass the future technical screen. (see post meeting follow up on the additional data requirements).
- Taminco is in an agreement with Fine Agrochemical for the registration review of chlormequat chloride.
 - Fine Agrochemical is citing Taminco studies to support the current DCI for chlormequat chloride that was published on February 12, 2019.

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Commented [GC5]: I thought we retracted this statement and told the company we need the other studies to make a decision on the waiver.

Commented [GH6R5]: This is true. Jessica: can you retract this statement?

Commented [GC7]: The Agency will conduct a new technical screen at the time a new application is submitted to the agency to determine if the application is complete.

Post-meeting follow up:

- EPA followed up via email regarding the registration review of chlormequat chloride. The docket ID# is EPA-HQ-OPP-2015-0816. Per the DCI, some of the studies are due in 12 months and some are due in 24 months. Barring any time extensions, Taminco will be required to have data to support all studies that are due in 12 months, before they submit their Section 3 petition in early 2020. Taminco will be required to state in their application and on their data matrix how they intend to support the studies that are due in 24 months (February 12, 2021), as these studies will be due before their PRIA due date for their new application. Data to support the 24-month studies must be submitted to EPA before their new Section 3 petition is approved by the same due date listed in the DCI and before a regulatory decision is granted on the application for new uses.
 - Taminco currently has data to support all studies listed in the chlormequat chloride registration review, except the Algal Toxicity studies and the Tier II and Tier III honeybee studies. Per the deficiencies outlined by EPA, Taminco is conducting the Algal Toxicity studies. Taminco is waiting for feedback from EPA on the Tier I honeybee studies before any additional Tier II or Tier III honeybee studies are initiated.

Commented [GC8]: DCI? Decision?

Commented [GH9R8]: Jessica: when you state that you have the data to support all the studies, are you referring to all of the studies that were called in under the DCI? There were a lot of studies called in.

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